#### **REMARKS**

Claims 5 and 8-12 and 15-26 are all the claims presently pending in the application. Claims 1-4, 6-7 and 13-14 have been canceled. Claims 5, and 8-12 have been amended to more particularly define the invention. Claims 15-26 have been added to claim additional features of the invention. Attached hereto is a marked-up version of the changes made to the specification and claims by the current Amendment.

It is noted that the claim amendments are made only for more particularly pointing out the invention, and <u>not</u> for distinguishing the invention over the prior art, narrowing the claims or for any statutory requirements of patentability. Further, Applicant specifically states that no amendment to any claim herein should be construed as a disclaimer of any interest in or right to an equivalent of any element or feature of the amended claim.

Claims 5 and 8-12 stand rejected under 35 U.S.C. §101 as directed to unpatentable subject matter. Claims 5 and 8-12 stand rejected under 35 U.S.C. §112, second paragraph. Claims 5 and 8-12 stand rejected under 35 U.S.C. § 102(b) as being anticipated by Oliver et al. (U.S. 5,723,765).

These rejections are respectfully traversed in the following discussion.

#### I. THE CLAIMED INVENTION

The claimed invention (e.g., as recited in claim 5) is directed to DNA to which information is added. The DNA includes a gene portion including genetic information, a portion, other than the gene portion, including no genetic information, and a nucleotide sequence which is added to the portion including no genetic information, and includes source identification information for identifying a source of the genetic information in the gene portion.

Conventional DNA does not include any information therein to determine the source of genetic information (e.g., a value-added gene). Since DNA having such a value-added gene is easily copied, it is difficult to apply technical restrictions to the copying, by third parties, of value-added genes.

The claimed invention, on the other hand, includes <u>a nucleotide sequence which is</u> added to a portion of the DNA which includes no genetic information, and which includes

source identification information for identifying a source of the genetic information in the gene portion. This nucleotide sequence may be used to identify the source of genetic information, for example, when the DNA is copied by a third party. Therefore, the claimed invention helps to prevent illegal copying of such genetic information (e.g., a value-added gene).

# II. THE 35 USC §101 REJECTION

The Examiner alleges that the claimed invention, as recited in claims 5 and 8-12, is directed to non-statutory subject matter. However, Applicant submits that the subject matter of these claims is patentable.

Specifically, the Examiner states that "insertion of special and non-natural sequences is described in the specification but not particularly in the claims". Applicant points out, however, that the claims recite sequences that are not naturally-occurring in DNA. For example, claim 5 recites "a nucleotide sequence that comprises source identification information for identifying a source of genetic information". Applicant notes that such "source identification information" does not naturally-occur in DNA. Therefore, the claimed invention is <u>not</u> a naturally-occurring product and is patentable subject matter.

In view of the foregoing, the Examiner is respectfully requested to withdraw this rejection.

# III. THE 35 USC §112, SECOND PARAGRAPH REJECTION

Claims 5 and 8-12 stand rejected under 35 U.S.C. §112, second paragraph. The claims have been amended, above, to address the Examiner's concerns.

Specifically, the phrase "correlated with" has been deleted from the claims 5, 8 and 12, the phrase "transmitted by" has been deleted from claims 5 and 12, and "a cell constituting an organism" has been replaced with "a cell in an organism" in claim 12.

In view of the foregoing, the Examiner is respectfully requested to reconsider and withdraw this rejection.

#### IV. THE OLIVER REFERENCE

The Examiner alleges that Oliver teaches the claimed invention. Applicant submits, however, that there are elements of the claimed invention which are neither taught nor suggested by Oliver.

Oliver discloses a method for making a genetically modified plant. The method includes regenerating a whole plant from a plant cell that has been transfected with DNA sequences including a first gene whose expression results in an altered plant phenotype linked to a transiently active promoter. Oliver also discloses a method for making a genetically modified hybrid plant by hybridizing a first plant regenerated from a plant cell that has been transfected with DNA sequences comprising a first gene whose expression results in an altered plant phenotype linked to a transiently active promoter (Oliver at Abstract).

However, contrary to the Examiner's allegations, Oliver does not teach or suggest "a nucleotide sequence which is added to said portion including no genetic information, and comprises source identification information for identifying a source of said genetic information in said gene portion" as recited in claims 5 and 12 and similarly recited in claim 8. As noted above, conventional DNA does not include any information therein to determine the source of a value-added gene. Since DNA having such a value-added gene is easily copied, it is difficult to apply technical restrictions to the copying, by third parties, of such value-added genes (Application at page 1, line 8-page 3, line 8).

The claimed invention, on the other hand, includes a nucleotide sequence which is added to a portion of the DNA which includes no genetic information, and which includes source identification information for identifying a source of the genetic information in the gene portion (Application at page 11, lines 1-21; page 16, line 8-page 16; page 20, line 6-page Figure 3). This nucleotide sequence may be used to identify the source of genetic information, for example, when the DNA is copied by a third party. Therefore, the claimed invention helps to prevent illegal copying of the value-added gene (Application at page 11, lines 9-21).

Clearly, these novel features are not taught or suggested by Oliver. Indeed, as noted above, Oliver teaches a method in which a cell is transfected with <u>a gene</u> whose expression results in an altered plant phenotype operably-linked to a transiently active promoter (Oliver

at col. 35, lines 17-18). This is completely different from the claimed invention which includes a nucleotide sequence which is added, not to a gene portion of the DNA, but to "said portion including no genetic information" as recited, for example, in claim 5. Further, unlike Oliver where a transiently active promoter is "operably-linked" to the gene, in the claimed invention, the nucleotide sequence added to the second portion of the DNA may not be "operably-linked" to any part of the genetic information in the first portion of the DNA. Therefore, Oliver is clearly not applicable to the claimed invention

Moreover, the Application clearly identifies Oliver as prior art and clearly explains the differences between Oliver and the claimed invention (Application at page 18, line 12-page 19, line 16). As explained in the Application, in Oliver a "toxic gene" and promotor are used to kill the embryo buds of the plant. However, how such a "toxic gene" affects humans and other animals that ingests the toxic protein generated by this gene is unknown.

In addition, in Oliver, the "toxic gene" is not expressed without the application of an external stimulus (Oliver at col. 2, lines 19-20). Further, the Oliver method requires a function that depends on the organism (e.g., activating a promoter when an embryo is developed). The claimed invention, on the other hand, does not require such a function and, therefore, can be used for a variety of organisms (Application at page 19, lines 11-16).

Moreover, in the claimed invention, the added nucleotide sequence includes "source identification information for identifying a source of said genetic information in said gene portion". The Examiner apparently equates the promoter in the Oliver method, with such source identification in the claimed invention. However, this is clearly incorrect.

Indeed, the promoter and the gene in Oliver may be "operably-linked". However, this does not mean that the promoter necessarily says something about the source of the "toxic gene" to which the promoter is linked. For example, nowhere does Oliver teach or suggest detecting the promoter and using it to identify the source of the "toxic gene". Indeed, Applicant notes that the purpose of the promoter is to terminate embryogenesis upon the application of external stimulus. In other words, there will eventually be no progeny to copy in Oliver and, therefore, no reason to identify the source of the "toxic gene" to prevent illegal copying by a third party.

Further, on page 5, second paragraph of the Office Action, the Examiner states that

"Lea promoter containing a specific known sequence ... is inherently correlated with information pertaining to the gene transmitting genetic information". The phrase "specific known sequence" in this passage seems to indicate "primer" which is naturally-organized nucleotide sequences.

However, in the claimed invention, the phrase "special sequence" may be intended as totally an artifact. Indeed, it may be artificially-designed so that it is very unlikely to be found in a natural organism. Further, if the special sequences are fixed, as in the Oliver method, the information with which the sequence is correlated must be common to all instances of the organism.

Oliver's method is applicable to the cases where one wants to mark each instance with the source of genetic information. However, in the claimed invention, by freely designing the sequence, each instance can be associated not only with the source of genetic information, but also with some additional information, especially information related to each instance (e.g., serial number, name of rightful owner, and so on). From the viewpoint of digital watermarking, the former would be considered "watermarking", and the latter would be considered "fingerprinting". Thus, the claimed invention, on the other hand, is different from Oliver's method at least in that the claimed invention can also be used for fingerprinting.

Further, on page 5, third paragraph of the Office Action, the Examiner states that "where the gene is expressed when a 'transiently-active promoter becomes active in the normal course of growth and development' ... which the Examiner interprets to mean the promoter does not affect the regular transmission of genetic information by the gene".

However, an important distinction between the claimed invention and the Oliver method, is whether the gene expression is used as a method of extracting correlated information. The Examiner seems to infer the safety of a "special sequence" from the fact that the promoter becomes active (and the gene is expressed) only transiently. However, the claimed invention does not intend the special sequences to change the function (e.g., the characteristics) of the organism at all. This may be realized by not associating the sequences with any genetic functions. Since the sequence has no meaning genetically, it can be concluded that it is harmless. Indeed, careful tests should be performed to check the safety of the inserted sequence.

On page 5, the fourth paragraph of the Office Action, the Examiner states that "[a]s each promoter may include a specific sequence with a specific nucleotide assembly pattern. the Examiner interprets the presence of several of these sequences to represent the 'multiple types of patterns". However, Applicant submits that even assuming, arguendo, that multiple types of patterns may be realized by Oliver, the efficiency attained by the claimed invention is different from that in Oliver.

As noted above, in the claimed invention, the special sequence may be artificially designed. Therefore there is a large degree of freedom. Further, this degree of freedom is directly related to how much information the sequence can be associated with.

In addition, in the claimed invention which may use artificial sequences, large amounts of image can be efficiently represented (e.g., with short special sequences and/or small numbers of multiple types) represented in DNA.

Therefore, Applicant submits that there are elements of the claimed invention that are not taught or suggest by Oliver. Therefore, the Examiner is respectfully requested to withdraw this rejection.

## V. FORMAL MATTERS AND CONCLUSION

In view of the foregoing, Applicant submits that claims 5 and 8-12 and 15-26, all the claims presently pending in the application, are patentably distinct over the prior art of record and are in condition for allowance. The Examiner is respectfully requested to pass the above application to issue at the earliest possible time.

Should the Examiner find the application to be other than in condition for allowance, the Examiner is requested to contact the undersigned at the local telephone number listed below to discuss any other changes deemed necessary in a <u>telephonic or personal interview</u>.

09/870,009 YOR.418

The Commissioner is hereby authorized to charge any deficiency in fees or to credit any overpayment in fees to Assignee's Deposit Account No. 50-0510.

Respectfully Submitted,

Date:

Phillip E. Miller Reg. No. 46,060

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09/870,009 YOR.418

## **VERSION WITH MARKINGS TO SHOW CHANGES MADE**

#### IN THE TITLE:

Please amend the Title to read as follows:

NUCLEOTIDE SEQUENCE FOR IDENTIFYING A SOURCE OF GENETIC INFORMATION, AND DNA AND CELL INCLUDING THE SAME

#### **IN THE SPECIFICATION:**

Please amend the paragraph beginning at page 6, line 15 to read as follows:

Further, according to the present invention, a method is provided for employing the information thus inserted into DNA to identify the source of genetic information in DNA that has been obtained from a predetermined organism. Specifically, this method comprises the steps of: obtaining DNA from an arbitrary organism of the same species as an organism wherein a source identification nucleotide sequence[,] for designating the source of genetic information [,] is embedded into the DNA[;], and employing as the source identification nucleotide sequence a complementary nucleotide sequence in order to determine whether the source identification nucleotide sequence is present in the DNA of the arbitrary organism.

#### **IN THE CLAIMS:**

Please cancel claims 1-4, 6-7 and 13-14 without prejudice or disclaimer.

## Please amend the claims to read as follows:

- 5. (Amended) [A] DNA to which information is added comprising:
  - a gene portion including genetic information; [and]
  - a portion, other than said gene portion, including no genetic information[,] :and

[wherein said portion other than said gene portion includes] a nucleotide sequence which is added to said portion including no genetic information, and comprises [that is correlated with] source identification information for identifying [and specifies] a source of

said genetic information in [that is transmitted by] said gene portion.

8. (Amended) DNA comprising: [wherein a]

at least one special sequence that is intentionally designed and is included as a part of a nucleotide sequence[;],

wherein said <u>at least one</u> special sequence <u>comprises</u> [is correlated with] source identification information for <u>identifying</u> [designating] the source of genetic information included in said DNA, [;] and

wherein said <u>at least one</u> special sequence is embedded in said DNA so as not to affect the transmission of said genetic information included in said DNA.

- 9. (Amended) The DNA according to claim 8, wherein [multiple of] said at least one special sequence comprises a plurality of sequences [are] embedded at predetermined locations of said DNA.
- 10. (Amended) <u>The DNA according to claim 8, wherein said at least one special sequence comprises a plurality of sequences having a plurality of [multiple] types of patterns [are] embedded at predetermined locations of said DNA.</u>
- 11. (Amended) A nucleotide sequence in [constituting one part of] DNA, comprising: [being correlated with]

source identification information for <u>identifying</u> [designating] a source of genetic information in <u>said DNA</u>, [and being]

wherein said information is embedded in said DNA so as not to affect transmission of said genetic information in said DNA.

- 12. (Amended) A cell <u>in</u> [constituting] an organism, <u>said cell having</u> [wherein] DNA <u>comprising</u> [included in said cell comprises]:
  - a gene portion including genetic information;[, and]
  - a portion, other than said gene portion, including no genetic information; and

[wherein said portion other than said gene portion includes] a nucleotide sequence which is added to said portion including no genetic information, and comprises [that is correlated with] source identification information for identifying [and specifies] a source of said genetic information in [that is transmitted by] said gene portion.